

**Cost-Effectiveness of an Integrated Telemedicine-Home Visitation Program for  
Children with Medical Complexity: A Quality Improvement (QI) Pilot Project**

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On March 29, 2018, the Institutional Review Board from The University of Texas Health  
Science Center determined that this quality improvement project does not qualify as  
human subject research.

## Abstract

Children with medical complexity (**CMC**) account for <1% of all children but approximately 40% of all pediatric deaths and inpatient care spending in the U.S.<sup>1</sup> Optimizing their outcomes requires a comprehensive approach to augmenting care in all settings: clinic, hospital, and home. The *clinic* component of our comprehensive care (**CC**) program provides 24/7 access to an experienced team of primary care providers and subspecialists and reduced their serious illnesses and hospital and ICU days by 47-69% and health-system costs by >\$10,000 per child-year.<sup>2,3</sup> Our *hospital* component (inpatient consultation service) is further improving outcomes. Having improved both inpatient and outpatient care, we now propose to complete a 360 degree approach and by developing and rigorously assessing an integrated telemedicine-home-visitation program (**THVP**) to augment care for CMC in their homes to reduce the need for clinic visits as well hospitalizations. Building on prior experience in using telemedicine for children at UTH and evidence of benefits in other populations,<sup>4,5</sup> our providers will use a convenient, inexpensive, HIPAA-compliant telemedicine platform to make observations in the home to augment care, help address acute problems remotely at any hour, better coordinate care with healthcare personnel, and thereby reduce clinic visits, ED visits, and hospitalizations. Home visits will be conducted by a nurse home visitor whenever considered likely to be beneficial for any of the CMC and at least once by the primary care providers (**PCPs**) immediately following enrollment of new technology-dependent children following discharge home from the neonatal intensive care unit (**NICU**). To promote reimbursements and further grant funding, we will test the

integrated THVP in a randomized quality improvement (**QI**) pilot study to verify its effectiveness and cost-effectiveness in reducing total days of care outside the home.

## **Background**

Children with medical complexity (**CMC**) have one or more chronic illnesses, require treatment from multiple specialists, and often depend on medical technology for respiratory and nutritional support.<sup>6</sup> Their care is fragmented, ineffective, and inefficient,<sup>2,7</sup> and while they represent only 0.4% of all children in the U.S., they account for approximately 40% of pediatric deaths and hospital charges.<sup>6</sup>

Optimizing their outcomes is likely to require a comprehensive approach to their care in all settings: *clinic, hospital, and home*. Our team has developed effective programs for their clinic and hospital care and now propose to add an innovative program to improve care in the home and verify its incremental cost effectiveness.

Our *clinic* component is provided in our High-Risk Children's Clinic (**HRCC**), an enhanced medical home for CMC staffed by a highly experienced team of nurse practitioners, pediatricians, and pediatric subspecialists. The multiple features to promote prompt effective care at all hours include 24/7 cell-phone access to our PCPs. As shown in our randomized trial (funded by a CMS Health Care Innovation Award), this program reduced ED visits, hospital days, and ICU days by 47-69%, and health system costs by \$10,258 per child-year below that with usual care. This trial was published in JAMA,<sup>2</sup> highlighted by CMS, and attracted national attention as the most rigorous evidence to date supporting medical homes for patient group.<sup>8,9</sup> The remarkable cost effectiveness of this program was found in later cohort analyses to have been well

maintained or enhanced when the program was expanded to include all eligible CMC, including prior control children and new enrollees.<sup>3</sup>

Our *hospital* component is an inpatient consultation service in which our HRCC staff consult and follow their patients admitted to Children's Memorial Hermann Hospital (**CMHH**) to make treatment recommendations, coordinate care, and plan their discharge. We randomized half of HRCC patients to receive this service in pilot testing. Results indicate a major reduction in inpatient days for patients given the service vs. those not given the service: 289 vs. 615 total hospital days/100 child-years with a 95% (posterior) probability of reduced hospital days in Bayesian analysis. Having improved both inpatient and outpatient care, we now propose to develop and rigorously assess a novel integrated telemedicine-home-visitation<sup>1</sup> program (**THVP**) to also augment care for CMC in their home. We will test the program in a clinical trial to verify its effectiveness and cost-effectiveness in reducing total days of care outside the home and to augment clinical practice and health policy.

### **Rationale and Evidence Base**

As emphasized by Hoffman and Emanuel<sup>10</sup>:

*“Clinicians need to abandon their long-established approach of caring for patients in the hospital or the office...Patients spend most of their time away from the health care system and the focus has to be one of managing their health literally where they live*

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<sup>1</sup> After the approval of the study protocol, the home visitation component of the integrated intervention was deemed not to be feasible with the available resources and personnel and has not been implemented.

*with much more wireless monitoring, electronic and phone visits, at-home care, and patient engagement.”*

Reducing the need for care outside the home is likely to be especially beneficial for our CMC; >90% are Medicaid beneficiaries. Their parents have limited resources and many find it difficult or costly to miss work and travel to Texas Medical Center. Moreover, any time spent in a medical setting imposes a risk of acquiring serious, even life-threatening infections for CMC.

A systematic review by AHRQ in 2016<sup>11</sup> reported that: 1) telemedicine promotes positive outcomes for chronically ill adults but has received little study for CMC, and 2) research to identify cost-effective models of telehealth deserves high priority.

Home visits have been widely recommended to improve care and reduce clinic visits and hospitalizations.<sup>12-15</sup> However, systematic reviews of home visitation have emphasized the need for further study, particularly for socially high-risk children.<sup>13</sup>

To maximize the potential benefits, we will provide both interventions in an integrated program. We will randomize the CMC in our HRCC to receive either our usual complex care (UCC [including comprehensive outpatient care and inpatient consultation] or THVP (UCC plus this telemedicine-home-visitation program)

### **Study Hypotheses**

Primary Hypothesis. THVP will reduce days of care outside the home (in the clinic, ED, or hospital).

### Secondary Hypotheses.

- 1) THVP will reduce the rate of serious illness (death, PICU admission, or prolonged hospitalization >7 days);
- 2) THVP will reduce the rate and total number of ER visits;
- 3) THVP will reduce the rate and total number of admissions;
- 4) THVP will reduce the rate and total number of readmissions within 30 days of discharge;
- 5) THVP will reduce health system costs;
- 6) THVP will increase maternal rating on the National Survey of Children with Special Health Care Needs (NS-CHSCN) Section 4 (Access to care: Utilization and Unmet Needs) and on The Consumer Assessment of Healthcare Providers and Systems (CAHPS) Child 12-Month Survey;
- 7) The investigators will implement multiple program refinements in learning to optimize THVP.

### **Methods**

Population: Children treated in the HRCC (enrollment criteria: chronic condition;  $\geq 2$  hospitalizations, or  $\geq 1$  pediatric ICU admissions in the year prior to enrollment; and  $>50\%$  estimated risk of hospitalization in the year after enrollment). We will exclude HRCC patients with a do-not-resuscitate status seen for compassionate care and those without access to the Internet.

Enrollment and Randomization: The UTH institutional review board has reviewed this study and determined that it does not qualify as human subject research. As a result,

the study was registered within the UTH QI Project database. Partly because of differences in the number of routine visits, all eligible CMC will be stratified by age ( $\leq 2$  years or older), whether or not they are assigned to receive inpatient consultation from the HRCC personnel, and by baseline clinical risk (high risk if  $<$  expected median risk or very high risk if  $\geq$  expected median risk, as judged by the clinic's medical director [R. Mosquera] based on diagnoses and prior clinical course) and randomized to either THVP or UCC using a computer-generated algorithm in REDCap with variable block sizes. Randomization will occur at baseline for the existing HRCC patients, before NICU discharge for newly enrolled technology-dependent infants, and during the first clinic visit for new non-technology-dependent children. Patient enrollment will occur between August 23, 2018 and August 22, 2020.

Integrated Telemedicine-Home-Visitation Program: Our program is based on: **1)** published findings of telemedicine or home visits in chronically ill children with diabetes, hemophilia, or leukemia;<sup>5,13-15</sup> **2)** our collaboration with Dr. Harting in successfully using telemedicine for postoperative follow-up visits for approximately 40 children in the past 14 months; **3)** consultation from IT personnel at UTH (Andrew Streckfuss, MBA, Manager of IT Projects and Research) who have setup the Zoom platform at UTH. In refining the program during the project, we expect to interact with centers advancing telemedicine use for children with asthma, diabetes, hemophilia, or leukemia.<sup>4,5</sup>

Planned Telemedicine Features: We will use the Zoom Telehealth platform, a fully HIPAA-compliant and secure video conferencing software with complete end-to-end encryption. Because our clinic is already equipped with a smart television, web cameras, and an emergency iPhone, no additional equipment will be required. With the

help of HRCC staff, the families randomized to THVP will download a free Zoom application to any Android or iPhone, which almost all our patients already have.

Telemedicine, defined in this study as real-time patient-provider video encounters, will be utilized systematically following calls received by the PCPs during clinic hours from parents seeking medical advice or trying to schedule same-day appointments for their sick child and only when judged needed by the PCPs for phone calls to the HRCC cell phone on weeknights and weekends. It will also be used systematically for follow-up visits following hospital discharge and as needed for other scheduled follow-up appointments.

Home Visitation Features<sup>2</sup>. Home visits will be conducted by a nurse home visitor when needed for any of the CMC and by our primary care providers (**PCPs**) at least once shortly after discharge home from the hospital following enrollment of a new technology-dependent child. Visits will be scheduled at a time convenient for the family. When needed for clinical or safety concerns, the nurse visitor or the PCP will be joined by a respiratory therapist, dietician, social worker, or medical assistant. Home visits will not be conducted whenever the visitor(s) feel unsafe. In these circumstances, we will rely instead on telemedicine.

To promote care coordination and avoid fragmentation, the nurse visitor is expected to schedule the needed home visits about twice a week and to provide nursing care in the HRCC on the remaining weekdays. As an integral member of the clinic staff, the nurse

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<sup>2</sup> After the approval of the study protocol, the home-visitation component of the integrated intervention was deemed not to be feasible with the available resources and personnel and has not been implemented.



visitor will be able to familiarize with all the HRCC patients and, thus, better coordinate care during the home visits.

Before any planned home visits the clinic team will develop goals and a specific plan for each visit to meet the patient and families specific needs. The planning will be conducted during the weekly HRCC team immediately preceding the home visit.

During the home visit the providers will focus on:

(1) Home environment, to identify and address problems that compromise the patient's safety or health (e.g., allergens in the homes of children with severe asthma or poorly controlled allergies).

(2) Nutrition, to ensure that the child's nutritional needs are met, that any special diets are well understood and properly provided, and that weight gain is improving for children with failure-to-thrive.

(3) Medications, to ensure that they are given in the appropriate dose and schedule and not outdated, that important side effects are identified and addressed, and that any problems are well addressed.

(4) Medical equipment/supplies, to ensure that all necessary equipment (e.g. ventilators, monitors, nasogastric or gastrostomy tubes, catheters, indwelling vascular lines, or telemedicine equipment) is in proper working condition, and used appropriately

(5) Education and anticipatory guidance.

(6) Changes in medical condition, as identified based on information communicated in the meetings noted above.

(7) Care coordination, to remind the caregivers of upcoming appointments and schedule additional visits if needed.

The providers will promptly enter a note about the visit into the child's medical records and use telemedicine in the clinic to follow-up and assure that any problems identified are well addressed.

Blinding: While the families and HRCC staff cannot be blinded, the healthcare economist and the statistician will remain blinded to treatment group when performing the analyses.

Assessment of Outcomes: Days of care in the hospital is already collected by the research nurse who reviews the ED and admission logs of CMHH each weekday. The HRCC providers ask the parents at each visit about outside hospital services. Days of care in the clinic will be collected and recorded by the nurses. In addition, we will also continue to assess claims data from UT Physicians and the 14 Memorial Hermann Health System (**MHHS**) hospitals. Parental ratings of care will be obtained annually by research personnel uninvolved in the care.

Economic Evaluation and Statistical Analyses: The incremental costs of THVP vs. UCC will be assessed from a health system perspective. Hospital costs will be based on the costs obtained from the cost-accounting system of the 14 hospitals in the Memorial Hermann Hospital System. The costs at other hospitals outside MHHS will be estimated based on the mean costs of these encounters at MHHS. Clinic costs for comprehensive care will be estimated using the HRCC's total expenditures to account for the low

patient-to-PCP ratio and the provision of multiple non-billable services not included in estimates derived from conventional claims-based methods.

The personnel time for providing office visits at the HRCC will be assessed by time motion studies and will be multiplied by personnel unit costs and the observed number of HRCC visits occurring in each treatment group during the study. The personnel time cost devoted to providing inpatient consultation will be assessed by multiplying the mean time spent on hospital consultations by the number of hospital days at CMHH occurring in each treatment group and by personnel unit costs. For the THVP group, we will add the time spent providing telemedicine consultation by tabulating data on overall Zoom usage and multiplying it by personnel unit costs. THVP costs will also be augmented by the time devoted to home visitation, monthly fees for the Zoom licenses, and the HRCC staff time spent assisting patients with Zoom App installation and use.

The above clinic costs do not include some costs such as those of telephone consultations and of other clinic personnel. As a result, to capture the full costs of providing CC, the above clinic costs will be subtracted from the total HRCC expenditures and the otherwise unaccounted for CC costs will be allocated to patients based on their length of follow-up during the study period. All economic and statistical analyses will be conducted using multilevel generalized estimating linear model (GLM) models. Differences in costs between treatment groups will be assessed using a GLM model with log-link and gamma distribution. Number of days of care in a medical setting in the THVP and UCC groups will be compared using a negative binomial GLM model with log link. All the models will be adjusted for baseline risk, age  $\leq 2$  or  $> 2$  years, and within-family correlation.

We will perform Bayesian analyses to assess the effectiveness of the THVP in reducing treatment days outside the home relative to UCC (primary outcome) using a neutral prior probability. Given the favorable prior evidence of benefit from THVP in other conditions,<sup>4,11</sup> a skeptical prior is considered unnecessary. Based on our current number of patients and enrollment rates in the HRCC, we expect to randomize ~400 patients during the 2-year study for a total of ~800 child-years of follow-up. THVP will be considered beneficial if: a) Bayesian analyses indicate it has a >67% (2 in 3) probability of reducing treatment days outside the home; and b) there is no evidence of an increase in adverse secondary outcomes. If so, provision of THVP could be recommended simply to increase access to care for vulnerable, disadvantaged children.

Under predefined stopping rules, enrollment will cease if Bayesian analyses performed at the end of the 1<sup>st</sup> year identifies a 75% or greater probability that THVP results in reduced treatment days outside the home.

Frequentist analysis will also be performed. For days of care outside the home, power will be ~80% to identify 20% reduction from the mean value of 10 days in the clinic, ED, or hospital days per child-year in the past year (SD=10.5).

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